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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,265	10/07/2003	Michael Merves	A8130.0135/P135	3136

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,265

Applicant(s)

MERVES, MICHAEL

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 6 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because Figures 7-10 are illegible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 1, element 20, and Figure 7, element 90. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are

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required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 6 is objected to because of the following informalities: The phrase "a opened position" should read "an opened position". Change "a" to --an--. Appropriate correction is required.
4. Claim 14 is objected to because of the following informalities: The phrase "a opened position" should read "an opened position". Change "a" to --an--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lizardi (Patent No. 5,944,724).

Regarding claim 1, Lizardi discloses a suture device (Figure 6, element 10) comprising an elongated shaft (26) having a longitudinal axis (not labeled), a proximal end (portion adjacent element 22), and distal end (54). Figure 6 shows a handle (18) provided at the proximal end (portion adjacent element 22), and a cavity (34) within the handle for storing at least one strand of suture (14; column 4, lines 13-16).

Regarding claim 8, Figure 1 shows the at least one strand of suture (14) is further provided with a needle (16).

Regarding claim 9, Figure 7 shows the elongated shaft (26) is configured to accommodate an implantable device (12).

Regarding claim 10, Lizardi discloses the implantable device is a suture anchor (column 4, line 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 2-7, and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lizardi in view of Keane et al. (Publication No. US 2003/0204195 A1).

Regarding claim 2, Lizardi discloses a device as described above, wherein the cavity (Figure 1, element 34) is provided with a hatch (Figure 1, element 44). Regarding claim 3, Figure 1 shows the hatch (44) is a pivotable hatch, since it swings open on an axis via a resilient connecting member (48). Regarding claim 4, Figure 4 shows the hatch (44) forms an angle (not labeled) with respect to the longitudinal axis of the elongated shaft (26). Regarding claim 5, Figure 5 shows the hatch (44) forms a zero degree angle with respect to the longitudinal axis of the elongated shaft (26) when the hatch (44) is in a closed position. Regarding claim 6, Figure 4 shows the angle is different from a zero degree angle with respect to the longitudinal axis of the elongated shaft (26) when the hatch (44) is in an opened position. Regarding claim 7, Figure 4 shows the angle is of about 10 degrees to about 170 degrees with respect to the longitudinal axis of the elongated shaft (the angle shown is about 90 degrees).

Regarding claims 2-7, Lizardi does not disclose a tie-down bar attached to the hatch (42). Like Lizardi, Keane et al. disclose a suture device (Figure 2, not labeled). Unlike Lizardi, Keane et al. disclose a tie-down bar (Figure 3, not labeled; bar that runs through element 1) attached to a hatch (1; since the spool 1 covers an opening 13 in the handle 8). This configuration contributes to an effective way of holding and dispensing suture thread and suture thread with attached needles (paragraph 6). Therefore, to construct the device of Lizardi with a tie-down bar connected to a hatch as taught by

Keane et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate holding suture thread and to reduce the likelihood of tangles in the suture thread.

Regarding claim 11, Lizardi discloses a suture device (Figure 6, element 10) comprising an elongated shaft (26) having a longitudinal axis (not labeled), a proximal end (portion adjacent element 22), and distal end (54). Figure 6 shows a handle (18) provided at the proximal end (portion adjacent element 22), and a cavity (34) within the handle (18) for storing at least one strand of suture (14; column 4, lines 13-16) provided with at least one surgical needle (Figure 1, element 16). Figure 1 shows the cavity (34) is provided with a pivotable hatch (44), since the hatch (44) swings open on an axis via a resilient connecting member (48). Figure 5 shows the pivotable hatch (44) is configured to be integral with the handle (18) when the pivotable hatch (44) is in a closed position. Regarding claim 12, Figure 7 shows the at least one strand of suture (14) provided with the at least one surgical needle (16) is stored within the handle (18) when the pivotable hatch (44) is in the closed position. Regarding claim 14, Figure 4 shows the pivotable hatch (44) is not integral with the handle (18) when the pivotable hatch (44) is in an opened position. Regarding claim 15, Figure 4 shows the pivotable hatch (44) forms an angle (not labeled) with respect to the longitudinal axis of the elongated shaft (26) when the pivotable hatch (44) is in the opened position. Regarding claim 16, Figure 4 shows the angle is of about 10 degrees to about 170 degrees with respect to the longitudinal axis of the elongated shaft (the angle shown is about 90 degrees). Regarding claim 17, Figure 7 shows the elongated shaft (26) is configured to

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accommodate an implantable device (12). Regarding claim 18, Lizardi discloses the implantable device is a suture anchor (column 4, line 1).

Regarding claims 11-18, Lizardi does not disclose a tie-down bar attached to the hatch (44). Like Lizardi, Keane et al. disclose a suture device (Figure 2, not labeled). Unlike Lizardi, Keane et al. disclose a tie-down bar (Figure 3, not labeled; bar that runs through element 1) attached to a hatch (1; since the spool 1 covers an opening 13 in the handle 8). Regarding claim 13, Keane et al. disclose the at least one strand of suture (Figure 1, element 6) with the at least one surgical needle (7) is wrapped around the tie-down bar (since the bar runs through element 1) when the pivotable hatch (1) is in the closed position (closed position being defined as when the hatch 1 is inserted in the handle 8). This configuration contributes to an effective way of holding and dispensing suture thread and suture thread with attached needles (paragraph 6). Therefore, to construct the device of Lizardi with a tie-down bar connected to a hatch as taught by Keane et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate holding suture thread and to reduce the likelihood of tangles in the suture thread.

Regarding claim 19, Lizardi discloses a method comprising the step of providing a suture housing device (Figure 6, element 10), since the sutures are stored within the handle (18), comprising an elongated shaft (26) having a longitudinal axis (not labeled), a proximal end (portion adjacent element 22), and distal end (54). Figure 6 shows a handle (18) provided at the proximal end (portion adjacent element 22), and a cavity (34) within the handle (18) for storing at least one strand of suture (14; column 4, lines

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13-16) provided with at least one surgical needle (Figure 1, element 16). Figure 1 shows the cavity (34) is provided with a pivotable hatch (44), since the hatch (44) swings open on an axis via a resilient connecting member (48). Figure 5 shows the pivotable hatch (44) is configured to be integral with the handle (18) when the pivotable hatch (44) is in a closed position. Lizardi discloses the step of actuating (selectively positioning) the pivotable hatch (44; column 5, lines 19-21) so that the pivotable hatch (44) forms an angle with respect to the longitudinal axis of the elongated shaft (26; see Figure 4). Regarding claim 20, Lizardi discloses attaching a surgical needle (16) to the surgical suture (14; column 7, lines 19-20). Regarding claim 21, Lizardi discloses attaching an implantable device (suture anchor 12) to the surgical suture (immediate thread 14 is retained within the suture anchor 12; column 5, lines 33-36; column 6 line 67, and column 7 lines 1-2). Regarding claim 22, Figure 4 shows the angle is of about 10 degrees to about 170 degrees with respect to the longitudinal axis of the elongated shaft (the angle shown is about 90 degrees).

Regarding claims 19-22, Lizardi does not disclose a tie-down bar attached to the hatch (44). Like Lizardi, Keane et al. disclose a suture device (Figure 2, not labeled). Unlike Lizardi, Keane et al. disclose a tie-down bar (Figure 3, not labeled; bar that runs through element 1) attached to a hatch (1; since the spool 1 covers an opening 13 in the handle 8). Figure 1 shows the surgical suture (6) is coiled around the tie-down bar, since the bar runs through the center of the hatch (1) and the suture (6) is coiled around the hatch (1). Figure 5 shows the surgical suture (6) goes through the elongated shaft (since it passes through tip portion of shaft 9) when the hatch (1) is in the closed

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position (closed position being defined as when the hatch 1 is inserted in the handle 8). Regarding claim 13, Keane et al. disclose the at least one strand of suture (Figure 1, element 6) with the at least one surgical needle (7) is wrapped around the tie-down bar (since the bar runs through element 1) when the pivotable hatch (1) is in the closed position (closed position being defined as when the hatch 1 is inserted in the handle 8). This configuration contributes to an effective way of holding and dispensing suture thread and suture thread with attached needles (paragraph 6) by reducing the likelihood of tangling the thread. Therefore, to construct the device of Lizardi with a tie-down bar connected to a hatch as taught by Keane et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate holding suture thread and to reduce the likelihood of tangles in the suture thread.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
July 11, 2006

MT


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SUPERVISORY PATENT EXAMINER
7/18/06